UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

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VASCULAR SOLUTIONS LLC; ARROW INTERNATIONAL, INC.; TELEFLEX LLC; and TELEFLEX LIFE SCIENCES LIMITED;

Plaintiffs,

v.

MEDTRONIC, INC. and MEDTRONIC VASCULAR, INC.,

Defendants.

Case No. 19-CV-1760 (PJS/TNL)

ORDER

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J. Derek Vandenburgh, Tara C. Norgard, Joseph W. Winkels, Alexander S. Rinn, and Shelleaha L. Jonas, CARLSON, CASPERS, VANDENBURGH & LINDQUIST, P.A., for plaintiffs.

Kurt J. Niederluecke, Lora M. Friedemann, Laura L. Myers, and Anne E. Rondoni Tavernier, FREDRIKSON & BYRON, P.A., for defendants.

Plaintiffs Vascular Solutions, LLC, Arrow International, Inc., Teleflex LLC, and Teleflex Life Sciences Limited (collectively "Teleflex") bring this patent-infringement action against defendants Medtronic, Inc. and Medtronic Vascular, Inc. (collectively "Medtronic"). Teleflex claims that Medtronic's Telescope catheter infringes claims in seven patents that are directed to guide extension catheters used in interventional

cardiology procedures.[1] Medtronic counterclaims for declarations of non-infringement and invalidity.

This matter is before the Court on Teleflex's motion for a preliminary injunction. For the reasons that follow, the motion is denied.

*A. Standard of Review*

A court must consider four factors in deciding whether to grant a preliminary injunction: (1) the movant's likelihood of success on the merits; (2) the threat of irreparable harm to the movant if the injunction is not granted; (3) the balance between that harm and the harm that granting the injunction will inflict on the other parties; and (4) the public interest. *Dataphase Sys., Inc. v. C L Sys., Inc.*, 640 F.2d 109, 114 (8th Cir. 1981).[2] Preliminary injunctions are extraordinary remedies, and the party seeking such relief bears the burden of establishing its entitlement to an injunction under the *Dataphase* factors. *Watkins Inc. v. Lewis*, 346 F.3d 841, 844 (8th Cir. 2003).

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[1]The technology is described in a *Markman* order entered in another case involving some of the same patents. *See QXMédical, LLC v. Vascular Sols., LLC*, No. 17-CV-1969 (PJS/TNL), 2018 WL 5617568 (D. Minn. Oct. 30, 2018).

[2]Generally speaking, the Federal Circuit applies regional circuit law when reviewing the grant or denial of a preliminary injunction. *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1363 (Fed. Cir. 2017). But the Federal Circuit gives "dominant effect to Federal Circuit precedent insofar as it reflects considerations specific to patent issues." *Id.* (citation and quotation marks omitted).

*B. Likelihood of Success*

For purposes of this motion, Teleflex argues that it is likely to succeed in showing that Medtronic infringes claims in four of its patents: U.S. Patent Nos. RE45,380 ("RE'380"), RE45,776 ("RE'776"), RE47,379 ("RE'379"), and RE45,760 ("RE'760").

"To establish a likelihood of success on the merits, a patentee must show that it will likely prove infringement of the asserted claims and that its infringement claim will likely withstand the alleged infringer's challenges to patent validity and enforceability." *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1364 (Fed. Cir. 2017). The likelihood of success must be considered "in light of the presumptions and burdens that will inhere at trial on the merits." *Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1259 (Fed. Cir. 2012).

Ultimately, however, the burden remains with the patentee to establish its entitlement to a preliminary injunction. If the non-movant "raises a substantial question concerning either infringement or validity, *i.e.*, asserts an infringement or invalidity defense that the patentee cannot prove lacks substantial merit, the preliminary injunction should not issue." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350-51 (Fed. Cir. 2001) (citation and quotations omitted). "The showing of a substantial question as to invalidity . . . requires less proof than the clear and convincing showing necessary to establish invalidity itself." *Id.* at 1359.

1. Written Description

Medtronic argues that all of the asserted claims in the RE'776, RE'379, and RE'760 patents are invalid for lack of a written description.[3] In particular, Medtronic argues that the original written description of the invention discloses a side opening only in the substantially rigid portion of the catheter, yet Teleflex's asserted claims place the side opening outside of the substantially rigid portion.

The written-description requirement is set forth in 35 U.S.C. § 112(a):

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

Section 112(a) therefore requires *both* (1) a written description of the invention *and* (2) a written description of the manner and process of making and using it. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1344 (Fed. Cir. 2010) (en banc). In the context of a reissued patent, the necessary disclosure must appear in the original specification. *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 563 F.3d 1358, 1366 (Fed. Cir. 2009).

[3]For purposes of this motion, Teleflex asserts the following claims in these three patents: claims 25, 36, and 37 of the RE'776 patent; claims 25, 33, 34, 38, and 44 of the RE'379 patent; and claims 25, 28, 29, 32, and 48 of the RE'760 patent.

The purpose of requiring a written description of the invention "is to prevent an applicant from later asserting that he invented that which he did not; the applicant for a patent is therefore required to recount his invention in such detail that his future claims can be determined to be encompassed within his original creation." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003) (citation and quotation marks omitted).

The test for determining the adequacy of the written description is whether it "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad*, 598 F.3d at 1351. The adequacy of the written description is a question of fact and "varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." *Id.*

Medtronic's expert, Dr. Paul Zalesky, opines that the written description for the asserted patents does not reasonably convey to a person of ordinary skill in the art that the inventor had possession of catheters with openings in locations other than the substantially rigid portion. Zalesky Decl. ¶¶ 68-85. Pointing to the prosecution history of the RE'379 patent, Dr. Zalesky notes that the patent examiner rejected some of the

proposed claims on the basis that the original specification is "very clear" that the side opening must be located in the rigid portion. Zalesky Decl. ¶ 82; ECF No. 117 at 18-19.[4]

In response, Teleflex does not address whether a person of ordinary skill in the art would understand, based on the written description, that the inventor had possession of the claimed subject matter (that is, catheters with side openings outside of the substantially rigid portion) as of the filing date. Instead, Teleflex asserts that "there is nothing improper about presenting claims that are broader than the preferred embodiments" and that the only exceptions to this "general rule" are where the technology area is "highly unpredictable" and where the specification makes clear that the unclaimed aspect is "critical to the invention." ECF No. 183 at 16.

Teleflex mischaracterizes the law. While predictability and criticality can be relevant to the adequacy of the written description, the focus is on what the disclosure conveys to persons of ordinary skill in the art. *Ariad*, 598 F.3d at 1351. This inquiry—which, again, is a question of fact for the jury, *id.* at 1355—"will necessarily vary depending on the context," *id.* at 1351, and "the precedential value of cases in this area is extremely limited," *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1377 (Fed. Cir. 2017) (citation and quotation marks omitted). As the Federal Circuit stated in *Ariad*,

[4]When citing documents by ECF number, the Court cites the page number generated by the electronic docketing system rather than the document's internal pagination.

> [W]e do not try here to predict and adjudicate all the factual scenarios to which the written description requirement could be applied. Nor do we set out any bright-line rules governing, for example, the number of species that must be disclosed to describe a genus claim, as this number necessarily changes with each invention, and it changes with progress in a field.

*Ariad*, 598 F.3d at 1351.

Teleflex next argues that the specification explicitly discloses side openings in portions other than the "substantially rigid" portion, pointing to Figure 1 of the specification as an example. As can be seen in Figures 4 and 12 through 16, however, the side opening is actually in the rigid portion. Am. Compl. Ex. G Figs. 1, 4, 12-16; *see also* Hr'g Tr. 182 ("All of the embodiments disclose [the side opening] in what the patent is calling the rigid portion.").

Teleflex also points to Figures 10 and 11, which depict relief cuts in the rigid portion. Am. Compl. Ex. G Figs. 10, 11. Teleflex reasons that, because the relief cuts render the rigid portion more flexible, this amounts to a disclosure that the side opening need not be located in the rigid portion. The fact remains, however, that the only disclosed location for the side opening is in the rigid portion. Teleflex offers no evidence that the possibility of increasing the flexibility of the rigid portion would convey to a person of ordinary skill in the art that the side opening could be placed somewhere other than in that rigid portion.

Teleflex also points to the language of ¶ 8 of the written description, which states that the rigid portion "may" include a cutout and full-circumference portion (i.e., a side opening), suggesting that use of the permissive "may" indicates that the location of the side opening is not critical to the invention. *See* Am. Compl. Ex. G at 3:49-51. But rather than being an elliptical way of indicating that the side opening can appear outside of the rigid portion, the permissive language is more naturally read as indicating that the device may or may not include a side opening. In other words, while this language may suggest that the existence of a side opening is not critical, it cannot easily be read to indicate that, when a side opening exists, its placement is irrelevant. Setting that aside, criticality is simply one possible factor among many in the overall inquiry concerning whether a person of ordinary skill in the art would recognize, based on the written description, that Teleflex had possession of catheters with side openings located outside of the substantially rigid portion.

Although the record is somewhat thin, and although the Court is mindful of the parties' respective burdens on this issue, Medtronic has nevertheless raised a substantial question regarding the adequacy of the written description. Medtronic offers unrebutted expert testimony that the written description is inadequate and points out that a patent examiner was troubled by the same issue, which is at least circumstantial evidence of a problem. While it is true that the examiner ultimately

allowed the application, she did not offer a word of explanation for her volte-face on the written-description issue.

In contrast to Medtronic's evidence, Teleflex offers no evidence of what a person of ordinary skill in the art would understand the written description to disclose. To the contrary, Teleflex failed to address that issue in its memoranda or even identify it as the governing standard. As Medtronic has raised a substantial question with respect to the adequacy of the written description, and as Teleflex has offered nothing relevant in response, the Court cannot find that Teleflex is likely to succeed in defeating Medtronic's written-description validity challenge to the asserted claims of the RE'776, RE'379, and RE'760 patents.

2. Anticipation

Medtronic contends that most of the asserted claims are invalid as anticipated by U.S. Patent No. 7,736,355 ("Itou"). Niederluecke Decl. Ex. 1. For purposes of this motion, the parties agree that, if Itou qualifies as prior art, all asserted claims of the RE'380 patent[5] (as well as all other asserted claims, save three) would be anticipated by Itou. The parties' dispute, therefore, centers on whether Itou is prior art.

[5]As the Court has already found that Medtronic has raised a substantial question with respect to the validity of the asserted claims in the RE'776, RE'379, and RE'760 patents, the RE'380 patent is the only remaining patent at issue. For purposes of this motion, Teleflex asserts infringement of claims 12, 13, and 15 of the RE'380 patent.

Itou's September 23, 2005 filing date predates the May 3, 2006 filing date of Application No. 11/416,629, the common application from which the RE'380 patent and the other asserted patents descend. Under the applicable[6] version of 35 U.S.C. § 102, however, it is the invention date, not the filing date, that determines priority. Specifically, a patentee may claim priority to either of two earlier dates: (1) the date the invention was reduced to practice; or (2) the date that the inventor first conceived the invention, if the inventor thereafter exercised reasonable diligence in reducing it to practice. *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1577 (Fed. Cir. 1996). "Reasonable diligence must be shown throughout the entire critical period, which begins just prior to the competing reference's effective date and ends on the date of the invention's reduction to practice." *Perfect Surgical Techniques, Inc. v. Olympus Am., Inc.*, 841 F.3d 1004, 1007 (Fed. Cir. 2016).

As Medtronic has come forward with evidence of art that indisputably predates the RE'380 patent's filing date, Teleflex bears the burden of production to offer evidence showing an earlier invention date. *Mahurkar*, 79 F.3d at 1576-77. To be sure, Medtronic will bear the ultimate burden at trial to persuade the jury, by clear and convincing evidence, that Teleflex's invention date does *not* precede September 23, 2005. *Id.*

[6]Because the common application that led to the family of patents at issue in this case was filed before March 16, 2013, the pre-America Invents Act version of § 102 applies. *Quest Integrity USA, LLC v. Cokebusters USA Inc.*, 924 F.3d 1220, 1225 n.1 (Fed. Cir. 2019).

at 1578. As noted, however, Medtronic's burden is somewhat lower at this stage; Medtronic need only raise a substantial question as to invalidity that Teleflex cannot prove lacks substantial merit. In that regard, it is important to recognize that Medtronic has already cleared a major hurdle, as it is undisputed that, if Itou does constitute prior art, it anticipates the RE'380 patent.

Teleflex relies on the testimony of Howard Root, one of the inventors of the patented device. But to establish an earlier invention date, an inventor's testimony must be supported by corroborating evidence. *Id.* at 1577 (conception); *Perfect Surgical*, 841 F.3d at 1007 (diligence); *Loral Fairchild Corp. v. Matsushita Elec.*, 266 F.3d 1358, 1363 (Fed. Cir. 2001) (reduction to practice). The parties dispute whether Teleflex has offered sufficient evidence to corroborate Root's testimony regarding diligence and reduction to practice.

Root attests that the invention was conceived by the beginning of 2005 and that it had been reduced to practice by at least August 2005, at which point the inventors had built and tested multiple different prototypes. Root Decl. ¶¶ 6-7, 42. To corroborate Root's testimony, Teleflex offers various invoices, lab notes, memos, photographs, and other supporting documents.

Medtronic points out, however, that during 2005 and 2006, the inventors were working on two different types of catheters: an over-the-wire ("OTW") version and a

rapid-exchange ("Rx") version. Root Decl. ¶ 11; *see* Zalesky Decl. ¶¶ 21-22 (describing the difference between the two types). The invention at issue here is the Rx version of the catheter, but, as Medtronic correctly notes, much of Root's declaration, and much of the supposedly corroborating documentation, speaks generically of the GuideLiner catheter without specifying whether it is referring to the OTW version or the Rx version.

More importantly, as Medtronic also points out, there is a remarkable discrepancy between the robust documentation of the development of the OTW version and the meager documentation that Teleflex has submitted to corroborate the reduction to practice of the Rx version. Teleflex has not submitted any laboratory notes, testing results, or prototype build records relating to an actual prototype of the Rx design.[7] In fact, Teleflex has not submitted any primary documents of the type that the Court would expect to see to corroborate the creation of an Rx prototype. Instead, Teleflex has relied primarily on invoices and payment records for component parts and other materials; more than half of the 60 exhibits that Teleflex has submitted consist of such documents. Yet, with respect to the majority of those documents, Teleflex does not

[7]Teleflex has submitted laboratory and other notes that document conception. *See* Root Decl. Exs. 1, 2. As noted, however, conception is not in dispute for purposes of this motion. Teleflex also contends that certain laboratory and other notes for the OTW version are also relevant to the Rx version, either because the experiments documented therein would be relevant to both versions, or because the "OTW" designation is mistaken. *See* Root Decl. ¶¶ 48, 57, 59 & Exs. 34, 41, 43. Teleflex may be correct, but there is at least a substantial question concerning the weight to be given to such documents.

claim anything more than that these components were for GuideLiner prototypes or devices. *See* Root Decl. ¶¶ 20-25, 27, 33-35, 46, 54-55, 60, 63-66, 70-71, 75. As it is clear that Teleflex was performing substantial work on the OTW version of the Guideliner, these documents do little to corroborate either diligence or reduction to practice of the Rx version.

Aside from these records, Teleflex submits various corporate documents, such as budget reports, marketing feasibility documents, legal bills, and other assorted memoranda that mention GuideLiner catheters. Again, though, a number of these documents appear to relate to the GuideLiner brand generally (or to the OTW version specifically) without referring to the Rx version. *See, e.g.*, Root Decl. Exs. 4, 19, 52, 58. And the documents that discuss the Rx version mostly seem to indicate that work was in the preliminary stages. *See*, *e.g.*, Root Decl. Exs. 2, 17, 20, 28, 29, 37, 40. Notably, a report dated December 1, 2005—months *after* Teleflex's claimed reduction to practice—states that "[t]he rapid exchange version requires additional engineering and is not included in our 2006 forecasts." Root Decl. Ex. 40.

To be sure, the record contains some scattered references to Rx prototypes and testing. *See, e.g.*, Root Exs. 36, 42. But these references are often ambiguous and could be read to refer to other types of catheters. Moreover, the types of documents in which these references appear only serve to highlight the lack of primary documentation that

would typically be generated during the development and testing of a medical device. The dearth of such documentation, coupled with the unimpressive nature of the corroborating documents that Teleflex submitted, means that Medtronic has more than met its burden to raise a substantial question as to the status of Itou as prior art (and therefore as to the validity of the RE'380 patent).

*C. Other Factors*

Because Medtronic has raised substantial questions concerning the validity of all of the asserted patent claims, Teleflex is not entitled to a preliminary injunction. *Metalcraft*, 848 F.3d at 1364 ("A preliminary injunction should not issue if the accused infringer raises a substantial question concerning either infringement or validity." (citation and quotation marks omitted)). The Court also notes that Teleflex has failed to make a particularly compelling case that it is threatened with "substantial and immediate irreparable injury." *Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1374 (Fed. Cir. 2012) (citation and quotation marks omitted).

Teleflex's GuideLiner is a well-known and trusted product in a highly specialized and defined market consisting of extremely sophisticated consumers. Welch Dep. 94-96 (there are roughly 2000 "cath labs" in the United States in which GuideLiner could be used, and GuideLiner is a trusted, "staple" product in all of them). Teleflex claims that it has lost sales to Medtronic, but loss of sales is the quintessential

"reparable" injury, and Teleflex has shown itself perfectly capable of calculating the resulting losses. *See* Welch Dep. 71, 75, 80-82, 85, 90-92, 196, 288; Welch Decl. ¶¶ 49, 52; *see also Metalcraft*, 848 F.3d at 1368 ("Evidence of potential lost sales alone does not demonstrate irreparable harm.").

Teleflex is also well-positioned to weather any short-term losses, as GuideLiner has a high profit margin and as North American sales of GuideLiner comprise only a minuscule portion of Teleflex's business. Specifically, U.S. sales of GuideLiner made up less than 1.5% of Teleflex's revenues in 2018. Welch Dep. 69, 112-13, 259; Friedemann Ex. HHH ¶ 24. *Cf. TEK Glob., S.R.L. v. Sealant Sys. Int'l, Inc.*, 920 F.3d 777, 792 (Fed. Cir. 2019) (no error in finding threat of irreparable harm on basis of patentee's lack of diversification, which exposed it to a particular risk of lowered market share).[8]

Teleflex works hard to cloak reparable sales losses in irreparable garb. Predictably, Teleflex complains that its reputation and goodwill are at risk. But any threat appears highly speculative. Teleflex claims that doctors may attribute any

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[8]Citing *Robert Bosch LLC v. Pylon Manufacturing Corp.*, 659 F.3d 1142 (Fed. Cir. 2011), Teleflex argues that its size and the relatively minor impact of lost GuideLiner sales on the company as a whole are legally irrelevant. The Court disagrees. In *Bosch*, the district court "erred in relying *exclusively* on the presence of additional competitors and on the non-core nature of Bosch's wiper blade business" in the face of "overwhelming evidence" of irreparable harm. *Id.* at 1150-51 (emphasis added). Moreover, by emphasizing the threat allegedly posed by Medtronic's size and resources, Teleflex itself put at issue its own size and the relative importance of GuideLiner to its overall operations.

problems with Medtronic's Telescope to GuideLiner, but Teleflex does not identify any such problems—and, as noted, GuideLiner is a well-known and trusted product.

Teleflex also cites a litany of other potential harms, such as a reduced sales force, lost sales of other Teleflex products, and a shrinking R&D budget—the types of harms that could be claimed by most patentees in most cases involving lost sales. Again, though, Teleflex's claims are highly speculative. Teleflex has not actually lost any sales representatives, and Teleflex cannot identify any lost sales of other Teleflex products. Welch Dep. 239, 326-27. Moreover, Teleflex's R&D budget is based on revenue for the entire North American interventional business unit, not just revenue from GuideLiner. Welch Dep. 330. It therefore appears to the Court that any harm that Teleflex may suffer during the pendency of this case will be reparable with money damages.

As for the remaining factors: In the absence of a likelihood of success on the merits, the public interest weighs against limiting competition and in favor of permitting the sale of potentially lifesaving medical devices. *See* Cardoso Decl. ¶ 9 & Ex. B (survey results with positive feedback from doctors about Telescope). That leaves the balance of harms. Even assuming that this factor weighs in Teleflex's favor, it cannot by itself justify a preliminary injunction.

For these reasons, Teleflex's motion for a preliminary injunction is denied.

ORDER

Based on the foregoing, and on all of the files, records, and proceedings herein, IT IS HEREBY ORDERED THAT plaintiffs' motion for a preliminary injunction [ECF No. 73] is DENIED.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: April 9, 2020

s/Patrick J. Schiltz
Patrick J. Schiltz
United States District Judge